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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/859,604	05/17/2001	Jack R. Wands	21486-032 CIP	5006

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	17

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/859,604	Wands et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *35-44* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *35-44* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7, 10
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Acknowledgment is made of applicant's election without traverse of Group V, drawn to antibodies or fragments thereof, kits comprising said antibodies or fragments, and hybridoma cell lines.

2. Claims 1-34, 45 and 46 have been canceled. Claims 35 and 44 have been amended. Claims 35-44 are pending and examined on the merits.

Claim Objections

3. Claims 39-43 are objected to as not complying with 1.821(d) of the Sequence Rules and Regulations. When the claims of a patent application discusses a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of the Sequence Rules and Regulations, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims of the patent application. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 35, 39- 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35 and 44 are rendered vague and indefinite in the use of antibody designations 86A, 5C7 19B, HA386A, HA15C7 and HA219B as the sole means of identifying the claimed antibodies and hybridoma cell lines. The use of laboratory designations only to identify a particular antibody/cell line renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct hybridomas and antibodies.

Amendment of the claims to include the depository accession number of the mAb or hybridoma is required, because deposit accession numbers are unique identifiers which unambiguously define a given hybridoma and/or monoclonal antibody.

Claims 39-43 are rendered vague and indefinite in the reliance upon "HAAH" to define the protein to which the claimed antibodies bind as other laboratories could use the acronym HAAH to represent a different protein. Amendment of claim 39 to incorporate SEQ ID NO:2 would overcome this rejection..

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 35 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to provide an enabling disclosure without complete evidence either that the claimed biological materials are know and readily available to the public or complete evidence of the deposit of the biological materials.

The specification lacks complete deposit information for the deposit of the hybridoma cell line producing the monoclonal antibodies designated 5C7, 19B, 86A, HA15C7A, HA219B, HA386A. It is not clear that monoclonal antibodies or hybridoma cell lines possessing the identical properties of 5C7, 19B, 86A, HA15C7A, HA219B, HA386A are known and are publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of a cell line is an unpredictable event. Clark (Protein Engineering of Antibody Molecules for Prophylactic and Therapeutic Applications in Man, 1993, page 1) states

"The in vivo antibody response is heterogeneous and is made up of a large mixture of antibodies secreted from a polyclonal population of cells. In addition, because the differentiation of B cells involves the random rearrangements of gene segments and somatic mutation of these rearranged genes,....no two animals, even of an inbred strain will make an identical set of antibodies." Although the applicant has provided a written description of a method for selecting the claimed hybridoma cell lines and monoclonal antibodies, this method will not necessarily reproduce antibodies and hybridomas which are chemically and structurally identical to those claimed. It is unclear that one of skill in the art could derive antibodies and hybridomas identical to those claimed. Undue experimentation would be required to screen all of the possible antibody and hybridoma species to obtained the claimed antibodies and hybridomas.

If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney or record who has the authority and control over the conditions of deposit over his/her signature or registration number stating that the deposit has been accepted by an International Depository authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed from the depository as required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If deposits are made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the deposited hybridomas, HA15C7A, HA219B, HA386A, are producing the monoclonal antibodies

5C7, 19B, 86A, as described in the specification as filed and are the same as those deposited in the depository, stating that the deposited hybridomas are producing the identical monoclonal antibodies 5C7, 19B, 86A as described in the specification and were in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re: Lundak, 773 F. 2d.1216, 227 USPQ 90 (CAFC 1985) and 37 CRF 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Radosevich et al (Cancer Research, 1985, Vol. 45, pp. 5808-5812) as evidenced by Radosevitch (U.S. 6,166,176). Claim 36 is drawn to an antibody or antigen-binding fragment thereof, wherein said antibody binds to a polypeptide comprising the amino acid sequence of residues 386-291 of SEQ ID NO:2. Claim 37 is drawn to an antibody or antigen-binding fragment thereof, wherein said antibody binds to a polypeptide comprising the amino acid sequence of residues 573-579 of SEQ ID NO:2. Claim 38 is drawn to an antibody or antigen-binding fragment thereof, wherein said antibody binds to a polypeptide comprising the amino acid sequence of residues 613-620 of SEQ ID NO:2. Radosevitch et al (1985) discloses the monoclonal antibody 44-3A6 which reacts with a cell surface antigen on a human lung carcinoma cell line, A549. Radosevitch ('176) discloses that this antibody binds to an epitope from residues 117-123 of Labyrinthin, which has an identical

domain with HAAH (figure 3). . Monoclonal antibody 44-3A6 would therefore cross-react with the instant SEQ ID NO:2. Recitation of the limitations of "polypeptides comprising the amino acid sequence of residues X-Y" does not limit the claims to antibodies which directly bind to the fragments recited. When given the broadest reasonable interpretation the claims are drawn to an antibody which binds any protein which minimally comprises the recited amino acid sequences.

10. Claims 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Lavaissiere et al (Journal of Clinical Investigation, 1996, Vol. 98, pp. 1313-1323, reference CAD of the I.D.S. submitted July 25, 2001). The specific embodiments of the claims are recited above. Lavaissiere et al disclose the monoclonal antibody FB-50 which binds to HAAH (page 1316, second column, under the heading "Molecular cloning of the antigen: its identification as HAAH". Lavaissiere et al teach a monospecific antiserum directed against the carboxyl terminal catalytic domain of bovine HAAH, wherein said antiserum binds to human cells (page 1320, last line to page 1321, line 5 and Legend for figure 7). Lavaissiere et al teach that in the carboxyl terminal catalytic domain, HAAH has 90% identity with bovine AAH (page 1320, first column, lines 1-4 of the second paragraph). It is reasonable to conclude that this anti-serum is binding to HAAH on human cells. Recitation of the limitations of "polypeptides comprising the amino acid sequence of residues X-Y" does not limit the claims to antibodies which directly bind to the fragments recited. When given the broadest reasonable interpretation the claims are drawn to an antibody which binds any protein which minimally comprises the recited amino acid sequences. Further, the specification teaches on page 2, lines 11-13 that the FB50 antibody binds to residues 286-291 of SEQ ID NO:2. The disclosure of Lavaissiere et al would therefore anticipate claims drawn to an antibody or fragment thereof wherein said antibody binds to a polypeptide consisting of residues 286-291 of SEQ ID NO:2.

11. Claims 36-38 are rejected under 35 U.S.C. 102(a) as being anticipated by Carter et al (WO 99/01020).

The specific embodiments of claims 36-38 are recited above. Carter et al disclose monoclonal antibodies and single chain antibodies which bind to the proteins encoded by Gene 14 (page 25, line s 19-21, page 46, lines 23-31, page 83, line 5 to page 84, line 22 and page 102, lines 35-36). Carter et al disclose that the translation product of Gene 14 shares sequence homology with aspartyl beta-hydroxylase (page 24, lines 13-14). Carter et al disclose that the proteins encoded by Gene 14 include SEQ ID NO:90, SEQ ID NO:93 and SEQ ID NO:48 (page 24, lines 19-21, 23-24 and page 25, lines 5-6). Carter et al disclose a preferred epitope as SEQ ID NO:48. Residues 44-70, 85-109, and 53-70 of the instant SEQ ID NO:2 are identical to residues 1-27 of SEQ ID NO:48, residues 21-45 of SEQ ID NO:90 and residues 1-18 of SEQ ID NO:93. It is reasonable to conclude that the monoclonal antibodies or fragments thereof disclosed by Carter et al would also bind to SEQ ID NO:2 as protein sequences comprising 27, 25 and 18 amino acids are contained in the proteins encoded by Gene 14 and the instant SEQ ID NO:2. Further, Carter et al discloses SEQ ID NO:48 as comprising a preferred epitope and Carter et al defines an "epitope" a polypeptide fragment having antigenic or immunogenic activity in an animal, especially in a human and further defines an "antigenic epitope" as the region of a protein to which an antibody can bind (page 45, line 34 to page 46, line 1). Carter et al states that antigenic epitopes contain a sequence of at least 7, preferably nine and more preferable between about 15 to about 30 amino acids. The common polypeptide sequences comprise 27, 25 and 18 amino acids, falling within the range defined "more preferably" as an antigenic epitope. It is reasonable to conclude that monoclonal antibodies raised against SEQ ID NO:90, 48 and 93 of Carter et al would include monoclonal antibodies which bind to SEQ ID NO:2 as common antigenic epitopes are present within SEQ ID NO:2. Recitation of the limitations of "polypeptides comprising the amino acid sequence of residues X-Y" does not limit the claims to antibodies which directly bind to the fragments recited. When given the broadest reasonable interpretation

the claims are drawn to an antibody which binds any protein which minimally comprises the recited amino acid sequences.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radosevich et al (Cancer Research, 1985, Vol. 45, pp. 5808-5812) as evidenced by Radosevitch (U.S. 6,166,176) in view of Wels et al (U.S. 5,939,531) and Schlom (Monoclonal Antibodies: They're More and Less Than You Think, In: Molecular Foundations of Oncology, 1991, Ed. S. Broder, pp. 95-134) and Goldenberg (U.S. 4,735,210).

The specific embodiments of claims 36-38 are recited above. Claim 39 is drawn to a kit for detecting a tumor cell, comprising a monoclonal antibody that binds to an epitope of HAAH. Claim 40 embodies the kit of claim 39 further comprising a means for detecting binding of said

antibody to said tumor cell. Claim 41 embodies the kit of claim 40 wherein said means is a detectable marker. Claim 42 embodies the kit of claim 41 wherein said detectable marker is a radioactive compound.

Wels et al teach kits comprising recombinant antibodies for the qualitative and quantitative determination of the c-erbB-2 protein for the diagnosis and treatment of tumors (column 22, lines 1-16 and abstract). Wels et al teach that the kits further comprise buffers, detergents, pipettes, reaction vessels, calibration curves, instruction manuals and the like. Wels et al teach that an enzyme immunoassay would be carried out by coating a suitable carrier such as the plastic surface of a microtiter plate or a test tube, nitrocellulose sheets, glass or plastic beads with the monoclonal antibody of the invention, thus fulfilling the specific embodiments of claims 35 and 36 drawn to enzyme immobilization on a assay plate, assay well, a nitrocellulose membrane, and a bead (column 21, lines 10-19). Wels et al teach that the antibodies are specific for the extracellular domain of the c-erbB-2 protein (column 3, lines 53-54). Wels et al teach that the antibodies of the invention comprise single-chained antibodies (column 3, lines 12-18). Wels et al do not teach antibodies which bind to HAAH.

Radosevich et al (Cancer Research, 1985, Vol. 45, pp. 5808-5812) as evidenced by Radosevitch (U.S. 6,166,176) anticipates claims 29 and 43 for the reasons set forth in section 13 above. Radosevitch et al teach ('176) that the binding of the 44-3A6 monoclonal antibody was a marker for adenocarcinoma (column 3, line 50 to column 4, line 19) and that a diagnostic method can be carried out using known antibodies which bind to the Lab antigen which are labeled (column 12, lines 36-44). Neither Radosevitch (1985) nor Radosevitch ('176) specifically teach a kit comprising said antibody.

Schlom (Monoclonal Antibodies: They're More and Less Than You Think, In: Molecular Foundations of Oncology, 1991, Ed. S. Broder, pp. 95-134, especially page 122, first column, first full paragraph, lines 15-26) teaches the use of radioactively labeled monoclonal antibodies advantages of single-chained antibodies over parent monoclonal antibodies which include rapid

clearance from the blood and body to avoid unwanted by-stander tissue toxicity, reduced accumulation in the kidneys, especially in reference to the avoidance of renal toxicity associated with drug conjugated antibodies, increased penetration of tumor masses, reduced immunogenicity due to lack of antibody effector domains (page 122, second column, lines 2-23) and relative ease of production (lines 27-30).

Goldenberg teaches a method of positive imaging of a tumor in a subject comprising the administration of a tumor binding antibody or fragment thereof labeled with a magnetic-resonance imaging agent comprising Gd(III) or Fe(III) (claims 1, 3 and 13).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the monoclonal antibody 44-3A6, or a single chain fragment thereof, for the monoclonal antibodies disclosed by Wels et al in the method taught by Wels. It would be further obvious to label said antibody and single chain antibody with a detectable label comprising a radioisotope, as taught by Schlom or a magnetic resonance imaging agent, Gd(III) or Fe(III) as taught by Goldenberg.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Radosevitch on the presence of the antigen for 44-3A6 on adenocarcinoma cells and the teachings of Schlom on the advantages of a single chained antibody relative to the parent murine antibody in the detection and treatment of tumors, in addition to the relative ease of making said single chain antibody; and the teachings of Goldenberg on the usefulness of magnetic resonance imaging by anti-tumor antibodies labeled with Gd(III) or Fe(III) in the detection of tumors in situ.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentable distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. *In re Berg*, 140 F. 3d 1428, 46 USPQ2d 1226 (Fed Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

16. Claim 35 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31 and 31 of U.S. Patent Application No.09/903,248 because the instant claim in anticipated by the reference claim. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claim 39 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34, -36 and 54-58 of U.S. Patent Application No.09/903,248 because the instant claim in anticipated by the reference claims. This is a

provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 39-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34, -36 and 54-58 of U.S. Patent Application No.09/903,248 in view of Radosevich et al (Cancer Research, 1985, Vol. 45, pp. 5808-5812) as evidenced by Radosevitch (U.S. 6,166,176) in view of Wels et al (U.S. 5,939,531) and Schlom (Monoclonal Antibodies: They're More and Less Than You Think, In: Molecular Foundations of Oncology, 1991, Ed. S. Broder, pp. 95-134) and Goldenberg (U.S. 4,735,210).

Schlom teaches the improvements afforded by the substitution of antibody fragments such as Fab, (Fab)2 or single chain Fv for whole IgG molecules in diagnostic tumor targeting (page 97, second column, last paragraph).

Wels et al teach that an enzyme immunoassay would be carried out by coating a suitable carrier such as the plastic surface of a microtiter plate or a test tube, nitrocellulose sheets, glass or plastic beads with the monoclonal antibody of the invention (column 21, lines 10-19).

One of skill in the art would be motivated to make Fab, (Fab')2 and scFv fragments of FB50 due to the teachings of Lavaissiere et al on the FB50 monoclonal antibody and the teachings of Schlom on the general improvements afforded to diagnostic assays by substituting Fab, (Fab')2 and scFv fragments in place of whole IgG antibodies. One of skill in the art would have been further motivated to include a assay plate, assay well, a nitrocellulose membrane, and a bead to the claimed kits as Wels et al teach that these are suitable carriers for monoclonal antibodies used in immunoassays. One of skill in the art would have been motivated to use Gd(III) or Fe(III) as a detectable label for said antibodies in a kit for the detection of tumors in situ as taught by Goldenberg.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 36-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29, 42-44, 33, 48-52, 39-41 and 45-47 of U.S. Patent Application No.09/903,248. The reference claims are drawn to antibodies which bind to HAAH. For the reasons states above, recitation of the limitation "polypeptides comprising the amino acid sequence of residues X-Y" does not limit the claims to antibodies which directly bind to the fragments recited. When given the broadest reasonable interpretation the claims are drawn to an antibody which binds any protein which minimally comprises the recited amino acid sequences. Furthermore, reference claims 29, 42-44, 39-41, and 45-47 are drawn to the FB50 fragment, which for the reasons noted above, would specifically bind to a protein consisting of residues 286-291 of SEQ ID NO:2. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. All claims are rejected.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

June 15, 2003